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Customer No.: 07278

Docket No.: 06727/100J782-US4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Tamir B. David et al.

Serial No.: 10/719,659

Filed: November 20, 2003

For: SELECTIVE NERVE FIBER STIMULATION
FOR TREATING HEART CONDITIONS

October 7, 2004

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made

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the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed.

[] D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

- i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.).

- A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:
[SERIAL NO. & FILING DATE].

Applicant identifies these documents by attaching hereto copies of the forms PTO-892 and PTO/SB08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

[] 3. Document(s) _____ are not in the English language. In accordance with 1.98(c), Applicant states:

- [] An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- [] A concise explanation of the relevance of document(s) _____ is found in the attached search report (see MPEP § 609 A(3)x).
- [] A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- [] A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- [] A concise explanation of document(s) _____ can be found on the attached sheet.

[] 4. No explanation of relevance is necessary for documents in the English language (see MPEP § 609 A(3)).

[] 5. Other information being provided for the examiner's consideration follows: [A/An _____ Search Report, dated _____, which issued during the prosecution of _____ Application No. _____ which corresponds to the present application.]

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

(1) U.S. Patent Application Serial No. _____, filed _____.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

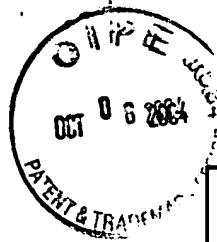


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October 7, 2004

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Substitute for form 1449A/B/PTO				Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/719,659-Conf. #2380
<i>(Use as many sheets as necessary)</i>				Filing Date	November 20, 2003
				First Named Inventor	Tamir B. David
				Art Unit	3762
				Examiner Name	Not Yet Assigned
Sheet	1	of	4	Attorney Docket Number	06727/100J782-US4

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
1**	US-6,341,236-B1	01-22-2002	Osorio		
2**	US-6,266,564-B1	07-24-2001	Hill		
3**	US-6,600,956-B2	07-29-2003	Maschino		
4**	US-5,540,730-B1	07-30-1996	Terry, Jr.		
5**	US-5,188,104-B1	02-23-1993	Wernicke		
6**	US-5,263,480-B1	11-23-1993	Wernicke		
7**	US-5,571,150-B1	11-05-1996	Wernicke		
8**	US-4,702,254-B1	10-27-1987	Zabara		
9**	US-4,867,164-B1	09-19-1989	Zabara		
10**	US-5,025,807-B1	06-25-1991	Zabara		
11**	US-6,205,359-B1	03-20-2001	Boveja		
12**	US-5,205,285-B1	04-27-1993	Baker, Jr.		
13**	US-5,299,569-B1	04-05-1994	Wernicke		
14**	US-5,335,657-B1	08-09-1994	Terry, Jr.		
15**	US-5,707,400-B1	01-13-1998	Terry, Jr.		
16**	US-5,282,468-B1	02-01-1994	Klepinski		
17**	US-4,628,942-B1	12-16-1986	Sweeney		
18**	US-4,535,785-B1	08-20-1985	van den Honert		
19**	US-4,602,624-B1	07-29-1986	Naples		
20**	US-5,199,430-B1	04-06-1993	Fang		
21**	US-5,215,086-B1	06-01-1993	Terry, Jr.		
22**	US-5,755,750-B1	05-26-1998	Petruska		
23**	US-4,649,936-B1	03-17-1987	Ungar		
24**	US-4,608,985-B1	09-02-1986	Crish		
25**	US-5,423,872-B1	06-13-1995	Cigaina		
26**	US-5,716,385-B1	02-10-1998	Mittal		
27**	US-6,097,984-B1	08-01-2000	Douglas		
28**	US-6,104,955-B1	08-15-2000	Bourgeois		
29**	US-6,091,922-B1	07-18-2000	Bisajji		
30**	US-5,836,994-B1	11-17-1998	Bourgeois		
31**	US-6,026,326-B1	02-15-2000	Bardy		
32**	US-6,083,249-B1	07-04-2000	Familoni		
33**	US-5,690,691-B1	11-25-1997	Chen		
34**	US-5,292,344-B1	03-08-1994	Douglas		
35**	US-4,962,751-B1	10-16-1990	Krauter		
36**	US-4,739,764-B1	04-26-1988	Lue		
37**	US-4,573,481-B1	03-04-1986	Bullara		
38**	US-5,540,734-B1	07-30-1996	Zabara		
39**	US-6,319,241-B1	11-20-2001	King		
40**	US-3,411,507-B1	11-19-1968	Wingrove		
41**	US-5,824,027-B1	10-20-1998	Hoffer		
42**	US-5,634,462-B1	06-03-1997	Tyler		
43**	US-2003/0229380-A1	12-11-2003	Adams et al.		
44**	US-4,585,005-B1	04/1986	Lue et al.		
45**	US-4,663,102-B1	05/1987	Brennan et al.		
46**	US-5,439,938-B1	08/1995	Synder et al.		
Examiner Signature				Date Considered	

Substitute for form 1449A/B/PTO				Complete If Known	
				Application Number	10/719,659-Conf. #2380
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				Examiner Name	Not Yet Assigned
Sheet	2	of	4	Attorney Docket Number	06727/100J782-US4

47**	US-5,454,840-B1	10/1995	Krakovsky et al.	
48**	US-5,938,584-B1	08/1999	Ardito et al.	
49**	US-6,169,924-B1	01/2001	Meloy et al.	
50**	US-4,338,945-B1	07/1982	Kosugi et al.	
51**	US-5,916,239-B1	06/1999	Geddes et al.	
52**	US-5,700,282-B1	12/1997	Zabara	
53**	US-5,690,681-B1	11/1997	Geddes et al.	
54**	US-5,199,428-B1	04/1993	Obel et al.	
55**	US-6,058,331-B1	05/2000	King et al.	
56**	US-6,230,061-B1	05/2001	Hartung	
57**	US-6,473,644-B1	10/2002	Terry, Jr. et al.	
58**	US-6,449,507-B1	09/2002	Hill et al.	
59**	US-6,356,784-B1	03/2002	Lozano et al.	
60**	US-5,832,932-B1	11/1998	Elsberry et al.	
61**	US-5,711,316-B1	01/1998	Elsberry et al.	
62**	US-6,094,598-B1	07/2000	Elsberry et al.	
63**	US-5,833,709-B1	11/1998	Rise et al.	
64**	US-4,559,948-B1	12/1985	Liss et al.	
65**	US-5,178,161-B1	01/1993	Kovacs	
66**	US-5,314,495-B1	05/1994	Kovacs	
67**	US-5,203,326-B1	04/1993	Collins	
68**	US-4,632,116-B1	12/1986	Rosen	
69**	US-4,019,518-B1	04/1977	Maurer et al.	
70**	US-6,091,977-B1	07/2000	Tarjan et al.	
71**	US-6,104,960-B1	08/2000	Duysens et al.	
72**	US-6,086,525-B1	07/2000	Davey et al.	
73**	US-4,926,865-B1	05/1990	Oman	
74**	US-4,392,496-B1	07/1983	Stanton	
75**	US-6,146,335-B1	11/2000	Gozani	
76**	US-6,119,516-B1	09/2000	Hock	
77**	US-5,069,680-B1	12/1991	Grandjean	
78**	US-6,366,813-B1	04/2002	Dilorenzo	
79**	US-6,405,079-B1	06/2002	Ansarinia	
80**	US-6,066,163-B1	05/2000	John	
81**	US-6,463,328-B1	10/2002	John	
82**	US-2004/0172075-A1	09-02-2004	Shafer et al.	
83**	US-6,511,500-B1	01-28-2003	Rahme	
84**	US-2003/0040774-A1	02-27-2003	Terry et al.	
85**	US-2003/0045909-A1	03-06-2003	Gross et al.	
86**	US-5,334,221-B1	08-02-1994	Bardy	
87**	US-5,356,425	10-18-1994	Bardy	
88**	US-5,522,854-B1	06-04-1996	Ideker et al.	
89**	US-6,434,424-B1	08-13-2002	Igel et al.	
90**	US-2002/0120304-A1	08-29-2002	Mest	
91**	US-6,006,134-B1	12-21-1999	Hill et al.	
92**	US-5,243,980-B1	09-14-1993	Mehra	
93**	US-5,658,318-B1	08-19-1997	Stroetmann et al.	
94**	US-6,292,695-B1	09-18-2001	Webster Jr., et al.	
95**	US-6,134,470-B1	10-17-2000	Hartlaub	

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Sheet	3	of	4	Attorney Docket Number	06727/100J782-US4

96**	US-2003/0050677-A1	03-13-2003	Gross et al.	
97**	US-6,610,713-B1	08-26-2003	Tracey	
98**	US-2004/0048795-A1	03-11-2004	Ivanova et al.	

**Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted

FOREIGN PATENT DOCUMENTS					
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
A	WO-01/10375-A2	02-15-2001	Impulse Dynamics NV		T ⁶
B	EP-0 688 577-A1	12-27-1995	Pacesetter AB		
C	WO-01/26729				
D	WO-01/10432				
E	WO-02/085448-A1				

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	F	Zhang, Y., et al., "Optimal Ventricular Rate Slowing During Atrial Fibrillation by Feedback AV Nodal-Selective Vagal Stimulation", Am. J. Physiol. Heart Circ. Physiol. 282:H1102-H1110, 2002.			
	G	Rijkhoff, N.J.M., et al., "Selective Stimulation of Small Diameter Nerve Fibers in a Mixed Bundle", Proceedings of the Annual Project Meeting Sensations/Neuros and Mid Term Review Meeting Neuros", pp. 21-23, April 1999.			
	H	Manfredi, M., "Differentiating Blocks of conduction of larger fibers in peripheral nerve by direct current", Arch. Ital. Biol., Vol. 108, pp. 52-71, 1970.			
	I	Fuster, Valentin, et al., "ACC/AHA/ESC Practice Guidelines", JACC, Vol. 38, No. 4, 2001.			
	J	Bilgutay, Aydin M., et al., "Vagal tuning a new concept in the treatment of supraventricular arrhythmias, angina pectoris and heart failure", J. Thoracic Cardiovasc. Surg., Vol. 56, No. 1, pp. 71-82, July 1968.			
	K	Friedrichs, Gregory S., "Experimental models of atrial fibrillation/flutter", Journal of Pharmacological and Toxicological Methods, 2000, Vol. 43, pp. 117-1123.			
	L	Hjalmarson, Ake, "Prevention of sudden cardiac death with beta blockers", Clin. Cardiol., 1999, Vol. 22, Supplement V, pp. V-11 - V-15.			
	M	Li, Danshi, et al., "Promotion of atrial fibrillation by heart failure in dogs", Circulation, July 6, 1999, pp. 87-95.			
	N	Kwan, Herman, et al., "Cardiovascular adverse drug reactions during initiation of antiarrhythmic therapy for atrial fibrillation", Can. J. Hosp. Pharm., 2001, Vol. 54, pp. 10-14.			
	O	Jideus, Lena, "Atrial fibrillation after coronary artery bypass surgery", Acta Universitatis Upsaliensis, Uppsala 2001.			
	P	Cummings, J.E., et al., "Preservation of the anterior fat pad paradoxically decreases the			

Examiner Signature	Date Considered
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				Examiner Name	Not Yet Assigned
Sheet	4	of	4	Attorney Docket Number	06727/100J782-US4

		incidence of postoperative atrial fibrillation in humans", J. Am. Coll. Cardiol., 2001, Vol. 43, No. 6, pp. 994-1000.	
	Q	Don W. Wallick, et al., "Selective AV nodal vagal stimulation improves hemodynamics during acute atrial fibrillation in dogs", Am J. Physiol Heart Circ Physiol, 281: H1490-H1497, 2001.	
	R	Masato Tsuboi et al., "Inotropic, chronotropic and dromotropic effects mediated via parasympathetic ganglia in the dog heart", Am J. Physiol Heart Circ Physiol, 279: H1201-H1207, 2000.	
	S	Chiou, C.W., et al., "Efferent vagal innervation of the canine atria and sinus and atrioventricular nodes", Circulation, 1997, Vol. 95, p. 2573.	
	T	P. Schauerte, et al, "Catheter stimulation of cariac parasympathetic nerves in humans", available at http://www.circulationaha.org , pp. 2430-2435, 2001.	
	U	M. Hirose, "Pituitary adenylate cyclase-activating polypeptide-27 causes a biphasic chronotropic effect and atrial fibrillation in autonomically decentralized, anesthetized dogs", The Journal of Pharmacology and Experimental Therapeutics, Vol. 283, No. 2, pp. 478-487, 1997.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Application No. (if known): 10/719,659

Attorney Docket No.: 06727/100J782-US4

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